



United States Department of Agriculture

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Food Safety and
Inspection Service

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ARGENTINA

Dear Ing. Agr. Guillen:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Argentina's meat inspection system from August 22 through September 7, 2012. Enclosed you will find a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, facsimile number (202) 720-0676, or by e-mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

ARGENTINA
FINAL AUDIT REPORT

July 24, 2014

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from August 22 - September 7, 2012, to verify whether Argentina's food safety inspection system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled. Argentina exports thermally processed, commercially sterile, heat-treated shelf stable, and fully-cooked not shelf stable meat products to the United States. Argentina is not allowed to export raw beef to the United States at this time because of Animal and Plant Health Inspection Service's (APHIS) restriction because Argentina has Foot and Mouth Disease.

The audit was designed to determine the equivalence of Argentina's meat inspection system and focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. FSIS also verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the last FSIS audit findings conducted from July 15 - August 18, 2009, were being implemented. An examination of Point-of-Entry (POE) findings since January 2012 showed no food safety violations.

The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Buenos Aires, the Cordoba regional office, along with two cattle slaughter and processing, and one cattle processing-only, establishments to verify that the national system of inspection, verification, and enforcement is being implemented as described by the CCA. Currently, Argentina has listed 14 establishments as certified eligible for export to the United States.

The onsite audit observations are summarized below and further addressed in the respective sections of the report:

- The inspection personnel in the two slaughter and processing establishments did not identify that the establishments' Specified Risk Materials (SRM) written control programs lacked measures to prevent the occurrence of, or to take corrective actions to prevent, carcass head contamination when brains of stunned cattle leaked from the knocking-hole.
- The inspection personnel in one slaughter and processing establishment did not verify whether cattle have access to water in holding pens. The auditor found that cattle in one of the holding pens did not have access to water. The establishment corrected this immediately.
- A discrepancy was noted in microbiological testing programs based on an audit observation that private laboratories are used for testing *Salmonella* samples which is not consistent with the United States criteria that Argentina committed to meet.

The CCA meets the criteria for all six equivalence components subject to it appropriately addressing this significant concern. It has had no POE refusals for more than one year. The CCA's food safety inspection system is operating at an "adequate" level of performance. However, the above observations indicate a need for improvement of the CCA's government oversight and the microbiological testing program. FSIS needs a response from Argentina within 60 days to support Argentina's ability to implement government oversight and microbiological testing programs that are equivalent to those of the United States. During the exit meeting, the CCA noted that it had taken immediate actions to address the above audit observations. FSIS will evaluate the corrective actions that the CCA presents.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of Argentina's meat inspection system from August 22 through September 7, 2012, to determine whether Argentina's food safety system governing the production of meat remains equivalent to that of the United States (U.S.), with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled.

Argentina is eligible to export beef products to the United States; however Argentina is not allowed to export raw beef to the United States at this time because of Animal and Plant Health Inspection Service's (APHIS's) restriction because of Foot and Mouth Disease. Argentina exports thermally processed shelf stable, heat treated shelf stable, and fully cooked not shelf stable beef products. Between January 1, 2013, and December 31, 2013, Argentina exported 3,286,187 pounds of beef products to the United States, of which 2,660,947 pounds were re-inspected at United States Point-of-Entry (POE). A total of 30 pounds were rejected at POE due to miscellaneous labeling issues. In calendar year 2012, Argentina exported 1,155,805 pounds of beef products of which 673,691 pounds were re-inspected. A total of 6,061 pounds was rejected at POE due to miscellaneous labeling issues. In calendar year 2011, Argentina exported 23,026,746 pounds of beef products, of which 17,666,470 pounds were re-inspected. A total of 12,668 pounds were rejected at POE due to miscellaneous labeling issues or transportation damage.

This audit was conducted pursuant to the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906)

The audit standards applied during this audit included all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process for Argentina, as well as any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Argentina's food safety inspection system governing meat products continues to be equivalent to that of the United States with the ability to produce and export meat products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objectives of determining whether each component continues to be equivalent to that of the meat inspection system of the United States. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. FSIS also verified that the corrective actions proffered by the Central Competent Authority (CCA) – the National

Service of Animal Health and Agro-Food Quality (*Servicio Nacional de Sanidad y Calidad Agroalimentaria- SENASA*) in response to the 2009 FSIS audit findings are being implemented.

III. AUDIT METHODOLOGY

For this equivalence verification audit, FSIS utilized its established four-phase process: plan, execution (onsite), evaluation, and feedback. Each phase is described below:

The first phase involved document and data analysis of previous audit findings and other available information. The FSIS auditor examined the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and self-reporting tool (SRT) data collected by FSIS since the last onsite audit in 2009. During the 2009 audit, no notice of intent to delist (NOID) or delistment was issued. However, the FSIS auditor reported problems in regard to sanitation and generic *E. coli* testing implementation, which was an indication of inadequate oversight by the CCA. During the 2012 audit, the FSIS auditor verified that previous problems were corrected, properly documented, and operating effectively.

Additional information reviewed by the FSIS auditor included responses by the CCA, outlining the current structure of the inspection system and identifying significant changes that have occurred since the last FSIS audit.

The second phase was the onsite verification. FSIS verified the CCA's oversight activities through onsite document reviews, interviews, observations, and site visits. The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Buenos Aires, the Cordoba regional office, and two bovine slaughter/processing and one processing-only establishments to verify that the national system of inspection, verification, and enforcement is being implemented as described by the CCA. During the establishment visits, particular attention was paid to the extent to which the CCA ensures the control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9 of the United States Code of Federal Regulations (CFR), section 327.2.

FSIS reviewed data from the chemical residue and microbiology laboratories. FSIS conducted onsite interviews with inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters, one regional office, and three audited establishments. In addition, FSIS conducted an onsite audit of the CCA residue laboratory in Buenos Aires, which is conducting analytical testing as part of Argentina's national residue program. FSIS verified the CCA's oversight activities related to the microbiology laboratory through review of available documents at the CCA and the Cordoba regional offices.

The third phase of the audit is evaluation. FSIS conducted an evaluation of all data collected onsite to verify whether the CCA's performance was consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

The final phase of the audit is feedback that begins with a draft audit report, which provides the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings,

FSIS prepares a final report. Then, the CCA develops an action plan to address any issues raised by the audit. These issues will be monitored by FSIS until resolution

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements for Argentina state that the foreign food safety inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States. The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices, one residue laboratory, and three audited establishments.

The CCA has the responsibility for implementing Argentina's meat inspection program including oversight and enforcement of the FSIS regulatory requirements in those establishments certified to export to the United States. The following is the organizational chain-of-command from the CCA's headquarters to the establishment's inspection offices:

- *Ministerio De Agricultura, Ganaderia y Pesce* or Ministry of Livestock and Fisheries;
- *Servicio Nacional de Sanidad y Calidad Agroalimentaria Unidad De Presidencia* or SENASA, Presidency Unit;
- *Dirección Nacional de Inocuidad de Calidad Agroalimentaria* or National Directorate of Agrifood Safety and Quality;
- *Dirección de Inocuidad de Productos de Origen Animal* or Directorate of Safety of Product of Animal Origin;
- *Coordinación General* or General Coordination;
- Coordination of Processing Establishments; Coordination of Slaughter Establishments; and Coordination of Poultry, Eggs and Game animals;
- *Dirección de Centros Regionales* or Regional Offices;
- Agrifood Safety and Quality;
- An Official Veterinary Inspector assigned at each United States-certified establishment; and
- Official Veterinary Assistants assigned at the United States-certified establishments.

The FSIS auditor interviewed the CCA officials at the headquarters and requested records related to implementation of corrective actions as applicable to FSIS 2009 audit findings. The auditor confirmed that the CCA had verified the implementation and effectiveness of the corrective actions.

The FSIS auditor interviewed the inspection personnel assigned to the audited establishments and verified the implementation of Argentina's Ministry of Agriculture and Livestock, Executive Decree No. 4.238, Chapter II, (2.1.1) and (2.2.27), which requires the CCA to maintain a single standard of laws and regulations applicable to all establishments certified for export to the United States.

FSIS noted that the inspection verification activities are conducted in an equivalent manner at all three of the audited establishments in accordance with uniform instructions distributed from the CCA to the field via e-mail, fax, telephone, and hard copies. The CCA publishes and disseminates updates and

additional instructions to inspection personnel concerning revised regulations or export requirements. These Circulars contain procedures to ensure that inspection personnel are applying a single standard of inspection while verifying the adequacy of food safety measures implemented at the United States-certified establishments. The CCA headquarters receives acknowledgement from regional offices and establishments upon receipt of these circulars as applicable at all levels.

During the headquarters audit, the FSIS auditor verified that the meat inspection program is funded from the National funds according to the Act 25.641 "National Institute of Agricultural Technology." The CCA deposits salaries from appropriated funds in employees' personal bank accounts. Each employee receives a salary receipt issued by the CCA. The CCA inspection officials shared the above information with the FSIS auditor and presented their receipts issued by the CCA.

Initial and ongoing certification of establishments for export to the United States is performed by the CCA's headquarters staff. The CCA's Executive Decree No. 4.238 and the Circular No. 3343 describe the regulatory requirements of Hazard Analysis and Critical Control Point (HACCP), Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), humane handling and slaughter requirements, and generic *E. coli* testing methodology. Those establishments that manufacture products intended for export are required to comply with the conditions and requirements of the country of destination or equivalent conditions and requirements in accordance with the CCA's Executive Decree No. 4.238, Chapter 1 (1.1.4.1) "Conditions or requirements for export." The FSIS auditor reviewed HACCP and SSOP programs developed by all three establishments audited. In addition, the auditor reviewed humane handling and generic *E. coli* programs developed by both slaughter establishments.

The CCA has the authority to require corrective actions in the United States-certified establishments and to take additional enforcement measures as appropriate in accordance with the CCA's Executive Decree No. 4.238. On October 7, 2011, the CCA delisted establishment No. 13 as a result of FSIS' notification for a second POE violation because of ivermectin. This establishment remains ineligible for export to the United States. The CCA's verification of ivermectin controls and further actions are addressed in the Chemical Residues Control Programs section of this report.

The FSIS auditor verified that the CCA's Executive Decree No. 4.238, Chapter VIII (8.1.1) is being implemented in the audited establishments. This Decree requires that the hygienic and sanitary surveillance of establishments be implemented by official veterinarians and assistants.

The CCA has an ongoing plan to continuously analyze and implement staffing requirements. The FSIS auditor verified that the inspection program's staffing in the audited establishments is in accordance with the CCA's Executive Decree No. 4.238, Chapter VIII "Official personnel/Veterinary inspection."

The CCA provides training to its inspection personnel in accordance with the CCA's Executive Decree No. 4.238, Chapter VIII. The CCA maintains a copy of all the training records or certificates. The FSIS auditor reviewed a sample of the training records or certificates during the onsite audit of the headquarters, Cordoba regional office, and inspection offices in each audited establishment. The calendar year 2012 training subjects included: food safety and quality, European Union issues, food safety update, food quality update, labeling, sanitation, and HACCP.

During the onsite audit of establishments, the FSIS auditor reviewed performance evaluation documents. These evaluations were conducted annually in accordance with the CCA's Decree 993/91. No concerns arose as a result of the reviews.

The CCA has the legal authority and responsibility to approve and disapprove laboratories conducting analytical testing on products for export to the United States. Direct oversight of private and government laboratories is performed by Directorate of Laboratories and Technical Control (DILAB) in accordance with the CCA's Resolution 736/2006. The FSIS auditor verified that the audited establishments are using private laboratories that are approved by the CCA-DILAB.

During the onsite audit of the Cordoba regional office, the FSIS auditor interviewed the inspection personnel and reviewed inspection documents including the regional organizational chart. There are four coordination departments and one regional laboratory in this region. Currently, there is only one United States-certified establishment in this region.

The ongoing analysis of available data and onsite audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. The CCA's control measures demonstrate that the CCA meets FSIS equivalence core criteria at an "average" level of performance for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. To be considered equivalent to FSIS' program, the inspection system must be designed and administered by the national government of the foreign country. The system must provide for humane handling and slaughter of livestock; ante-mortem inspection of animals or birds; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; and daily inspection and periodic supervisory visits to official establishments.

The FSIS auditor interviewed the inspection personnel at the CCA's headquarters, Cordoba regional office, and three audited establishments. The inspection personnel are employees of the national government. There have been no changes in the structure or the oversight function of the CCA since the last FSIS audit in 2009. The auditor noted that the CCA implements its inspection of meat and meat by-products in accordance with Acts No. 3959 and 11.226. The FSIS auditor reviewed inspection documents generated within the last three months. The review verified that the inspection personnel perform daily inspection verification activities in regard to HACCP, SSOP, and SPS requirements in audited establishments. No concerns were noted.

The FSIS auditor reviewed the CCA's Executive Decree No. 4.238, Chapter X, Ante-mortem inspection rules. The auditor also reviewed ante-mortem inspection records generated by the inspection personnel in the two slaughter/processing establishments audited. In addition, FSIS observed ante-mortem inspection examination. The auditor verified that the inspection personnel follow the CCA's regulatory requirements. At one of the two slaughter and processing establishments audited, FSIS noted that cattle in one of the holding pens did not have access to water. The establishment corrected this situation immediately.

The FSIS auditor reviewed the CCA's Executive Decree No. 4.238, Chapter XI, Post-mortem examination. The auditor also reviewed post-mortem inspection records generated by the inspection personnel in two slaughter/processing establishments audited. In addition, FSIS observed post-mortem inspection examination of carcasses, viscera and heads at the time of slaughter. The auditor verified that the inspection personnel follow the CCA's regulatory requirements. No concerns were noted.

The CCA's Executive Decree No. 4.238, Chapter II (2.1.1) provides the legal authority for the CCA's oversight controls over each establishment's construction, facilities, and equipment. During each establishment's audit, the FSIS auditor verified that the audited establishments are complying with the provision of these documents while the inspection personnel enforce the applicable requirements.

The CCA's Executive Decree No. 4.238, Chapter III (3.4), Circular No. 3580, and Circular No. 3528 provide the legal authority for the CCA's oversight over condemned materials until they are removed or destroyed. The FSIS auditor noted that the inedible and condemned product containers were properly labeled and color coded. The audited slaughter and processing establishments have rendering facilities that are operated by the establishments. The FSIS auditor reviewed inspection verification records, "Daily Condemned Bovine Records," concerning the disposition of the condemned products. No concerns were noted.

The Argentina meat inspection system has legal authority and a well-documented regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. The document analyses and onsite verification activities indicate that CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. FSIS concludes the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA must provide equivalence requirements for all areas of sanitation, sanitary handling of products, SPS, and SSOP. The FSIS auditor verified that the inspection personnel at the three audited establishments conduct verification of sanitary conditions in accordance with the following requirements:

- Executive Decree No. 4.238 (The Regulations for the Inspection of Products of Animal Origin, By-Products, and Derivatives);
- Executive Decree No. 4.238, Chapter III (Sanitary Building and Engineering of Slaughter Establishment);
- Executive Decree No. 4.238, Chapter XXXI (Good Manufacturing Practices and Standard Operating Procedures);
- Circular No. 3837 (Supplement to Circular No. 3271/97 – Company SSOP Implementation Procedures and Verification by the Veterinary Inspection Services);
- Circular No. 3297 (Guidelines for SSOP Evaluation and Verification - Pre-Operational and Operational Guidelines)

- Circular No. 3271 (Implementation of Sanitation Standard Operating Procedures by the establishments); and
- Circular No. 3259 (Future Application of the SSOP in the United States' Establishments)

This information supports that the CCA has the legal authority and responsibility to require that each certified establishment develop and maintain sanitation programs to prevent direct product contamination or the creation of insanitary conditions. The FSIS auditor reviewed each audited establishment's sanitation program and records generated within the last 90 days. No concerns were noted.

The FSIS auditor assessed the inspection personnel verification activities by reviewing each establishment's pre-operational and operational sanitation monitoring records and the inspection personnel verification records for these activities. In addition, the auditor observed the inspection personnel as they performed pre-operational and operational sanitation inspection verification. FSIS verified that the inspection personnel conduct pre-operational and operational sanitation verification on a daily basis as required by the CCA. The record review indicated that the inspection personnel identify and document their observations in an equivalent manner to FSIS' system.

The document analysis and onsite audit verification including observations, document reviews, and interviews demonstrate that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or an equivalent preventive control plan. The CCA's headquarters, one regional office, and three establishments were audited to verify whether the CCA maintains effective government oversight for the implementation of the CCA's meat inspection system and, in particular, HACCP requirements. The evaluation of this component included an analysis of the responses provided by the CCA in the HACCP portion of the SRT. The documents reviewed included:

- Circular No. 3531 (Updates for generic *E. coli* control; *E. coli* O157:H7 in trimmings or ground meat; *Salmonella* Control/Pathogen Reduction Program; HACCP compliance verification);
- Circular No. 3514 (*E. coli* O157:H7 as a Reasonable Hazard in the HACCP Plan);
- Circular No. 3390 (Checklist for Certification of Export Products);
- Circular No. 3353 (HACCP System- Basic Compliance Checklist); and
- Circular No. 3259 (Future Application of the HACCP in the United States' Establishments).

The FSIS auditor conducted onsite observations to assess the establishments' operation and inspection verification in accordance with the aforementioned requirements. The FSIS auditor verified through record reviews and observations that the inspection personnel at audited establishments conduct daily verification of HACCP including the evaluation of written HACCP programs; establishment monitoring, verification, corrective actions, and record keeping; and hands-on verification inspection of critical control point (CCP) for all production shifts. No concerns were noted.

FSIS verified that the establishments maintain documentation that includes flow of product charts, written hazard analysis, and associated documents that support decisions made to establish CCPs and critical limits. The establishments also generate and maintain records documenting the results of CCP monitoring activities and implement corrective actions when deviations occurred. No concerns were noted.

The FSIS auditor reviewed the CCA's Circulars No. 3528 and 3580, concerning requirements for handling, treatment, and disposal of bovine specified risk materials (SRM). In addition, the auditor reviewed daily inspection verification records and periodic supervisory review records generated by the Cordoba regional office. The CCA treats the brain as an SRM in cattle of 30 months of age or older. The two audited slaughter/processing establishments treat all cattle as 30 months of age or older in their operations. During the onsite audit of both slaughter and processing establishments, the FSIS auditor observed the leakage of brain tissues from the knocking hole of skinned heads resulting in carcass head contamination with SRM. A review of the establishments' SRM control programs showed that neither of the two establishments has written procedures to prevent brain leakage, nor has either taken corrective actions when brain leakage occurs. In addition, the inspection personnel did not identify or document this problem in inspection records, including periodic supervisory review records within the last 90 days. The periodic supervisory reviews, which are performed on a monthly basis by the regional supervisors, also missed this problem. The CCA realized the importance of this issue and implemented immediate corrective actions in audited establishments. In addition, the CCA instructed its inspection personnel to verify that establishments maintain required SRM control programs and take corrective actions, if applicable, in all of the United States-eligible establishments.

The one audited Ready-to-Eat (RTE) processing establishment producing beef jerky was following the monitoring and verification procedures outlined in its HACCP program for the lethality (water activity, cooking time, temperature, and humidity) and stabilization processing steps. Validation documentation was maintained to support the establishment's selection of the CCP and critical limits, as well as to demonstrate that these parameters were met in the production environment. The processing establishment producing cooked beef product in tubes was meeting the cooking and cooling requirements as written in its HACCP program. The FSIS auditor verified that this establishment was meeting the Animal and Plant Health Inspection System (APHIS) pink juice test requirements because of restrictions for Foot and Mouth Disease (FMD). This establishment exports fully-cooked product to the United States. No concerns were noted.

The document analysis and onsite audit verification including observations, document reviews, and interviews demonstrate that the CCA meets FSIS equivalence core criteria at an "adequate" level of performance for this component. However, FSIS observations indicate that the CCA needs to ensure the ability of its inspection personnel to verify the implementation of SRM control procedures and document all the findings in a consistent manner.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM

The FSIS auditor reviewed Chemical Residues Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent contamination of food products with chemical residues. To be considered equivalent to FSIS' residue control program, the

CCA's program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to assure the validity and reliability of test data.

The FSIS auditor verified that the CCA has a chemical residue control program, organized and administered by the national government. The Residue Control and Food Hygiene (CREHA) plan includes random sampling of internal organs and fat of carcasses for chemical residues. The 2012 CREHA residue sampling plan was being followed by the inspection personnel as intended in all three establishments audited.

The CCA had taken appropriate corrective actions for the verification of ivermectin due to 2011 POE violations and issued the CCA Circular Letter No. 3980, dated December 29, 2011. This Circular is being implemented in the United States-certified establishments and provides the following requirements:

- As a pre-condition of the HACCP plan, companies (meat processors) must maintain a list of authorized suppliers of cattle for the United States;
- The purchase of cattle at auction sales is prohibited;
- The companies are required to instruct their cattle suppliers of the need to meet drug withholding times and receive affidavits to this effect prior to slaughter;
- In case of violative results, in the course of official sampling, the company shall withdraw the offender from the list of authorized suppliers of cattle for the United States market;
- The veterinary inspection service shall continue to sample each production batch, and wait for a negative result for its certification;
- In case of violative results, the company shall withdraw the offender from the list of authorized suppliers of cattle for the United States market;
- In case of a first violative finding at the United States POE, the company must reassess its HACCP Plan, and Directorate for Animal Products Safety shall verify to assess the corrective measures; and
- In case of a second violation, not only the aforementioned corrective measures shall be taken, but certification of the exporting company shall also be suspended as a precautionary measure.

The FSIS auditor reviewed a list of authorized suppliers of cattle and verified the implementation of this Circular at the two slaughter and processing establishments audited. There has been no ivermectin residue violation on imported products from Argentina since the implementation of this Circular in 2011.

The FSIS auditor visited the "General Directorate of Laboratories and Technical Control" chemical residue laboratory located in Martinez. The auditor reviewed training records and certifications associated with the qualifications of the analysts. The onsite document reviews indicate that the laboratory analysts had successfully completed intra-lab and inter-lab evaluations administered by the laboratory supervisor and possessed the competencies necessary to conduct the analysis assigned to them. Additionally, sample handling and frequencies, timely analyses, data reporting, tissue matrices

for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control are performed in accordance with the CCA requirements.

The document analyses and onsite audit verification of the Chemical Residues Control Program component indicate that the CCA continues to perform at an “average” level in meeting FSIS’ equivalence criteria for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are unadulterated, safe, and wholesome and meet all equivalence criteria. The FSIS auditor assessed the implementation of the microbiology laboratory’s policies and procedures based on information obtained from interviews of inspection officials during the headquarters, regional office, and establishment visits.

The CCA has adopted the FSIS regulatory requirements for testing for generic *E. coli* and issued the CCA Circular No. 3259/96. The FSIS auditor reviewed the written generic *E. coli* program and the records of analytical testing results produced by the establishments for the previous 90 days. The auditor also observed quality control program employees collecting the sample from chilled beef carcasses using the aseptic sampling techniques at both slaughter/processing establishments. These reviews and observations indicate that both of the audited establishments are meeting the CCA’s regulatory requirements for testing for generic *E. coli*. No concerns were noted.

The CCA has adopted the FSIS *Salmonella* standards for raw intact beef meat products. The CCA issued Circular No. 3764, dated September 21, 2007, “*Salmonella* testing for the United States.” The establishments were evaluated according to the CCA’s regulatory requirements. The FSIS auditor verified that the sampling methodology is in accordance with the CCA requirements, including corrective and enforcement actions as appropriate. The CCA conducts *Salmonella* testing in United States –certified establishments. *Salmonella* samples are collected by inspection personnel and analyzed in private laboratories that are ISO 17025 accredited and certified by DILAB. The auditor noted a discrepancy in microbiological testing programs because of Argentina’s use of private laboratories for testing *Salmonella* samples which is inconsistent with the United States criteria that Argentina committed to meet. This discrepancy is a significant concern for FSIS. Argentina will need to address it expeditiously, as explained in the “Conclusions and Next Steps” section of this report, which follows.

The CCA has adopted FSIS regulatory requirements for the control of *Listeria monocytogenes* (*Lm*) and *Salmonella* in post-lethality exposed RTE products. The only audited processing establishment producing RTE (beef jerky) product is meeting the CCA’s regulatory requirements by adopting alternative 2B for the control of *Lm* in its product. The frequency of the CCA testing of product, food contact surfaces, and environmental testing is once a month for *Lm*, and testing of product for *Listeria spp.*, *Salmonella*, and *E. coli* O157:H7 is every two months. The CCA product verification samples for *Lm*, *Salmonella* and *E. coli* O157:H7 were found to be negative for calendar year 2012. No concerns were noted.

The document analyses and onsite audit verification of the Microbiological Testing Programs component indicate that the CCA continues to perform at an “adequate” level in meeting FSIS’ equivalence criteria for this component.

X. CONCLUSIONS AND NEXT STEPS

The CCA meets the criteria for all six equivalence components, with one significant reservation, and has no POE refusals for more than one year. The CCA’s food safety inspection system is operating at an “adequate” level in maintaining equivalence. However, the audit observations established that the CCA must improve its oversight and microbiological testing program. These observations were conveyed by the FSIS auditor to the CCA inspection personnel at an exit meeting on September 7, 2012, in Buenos Aires. The CCA understood and accepted the need to address the following observations:

- The inspection personnel in two slaughter and processing establishments audited did not identify that the establishments’ Specified Risk Materials (SRM) written control programs lacked measures to prevent the occurrence of, or to take corrective actions to prevent, carcass head contamination when brains of stunned cattle leaked from the knocking-hole.
- The inspection personnel in one slaughter and processing establishment did not verify whether cattle have access to water in holding pens. Cattle in one of the holding pens did not have access to water. This was corrected immediately.
- A discrepancy was noted in microbiological testing programs based on an audit observation that private laboratories are used for testing *Salmonella* samples which is inconsistent with the United States criteria that Argentina committed to meet. Argentina must address this discrepancy forthwith.

FSIS needs a response from Argentina within 60 days to support Argentina’s ability to implement government oversight and microbiological testing programs that are equivalent to those of the United States. During the exit meeting, the CCA noted that it had taken immediate actions to address the above audit observations. FSIS will evaluate the CCA’s corrective actions.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico "ESTANCIAS DEL SUR." Unquillo Cordoba Region	2. AUDIT DATE 08/29/2012	3. ESTABLISHMENT NO. 2065	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Farooq Ahmad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP			33. Scheduled Sample	
8. Records documenting implementation.			34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.			36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light	
14. Developed and implemented a written HACCP plan .			41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils	
18. Monitoring of HACCP plan.			46. Sanitary Operations	
19. Verification and validation of HACCP plan.			47. Employee Hygiene	
20. Corrective action written in HACCP plan.			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage	
23. Labeling - Product Standards			51. Enforcement	X
24. Labeling - Net Weights			52. Humane Handling	X
25. General Labeling			53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)			54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing			55. Post Mortem inspection	
27. Written Procedures			Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis			56. European Community Directives	O
29. Records			57. Monthly Review	
Salmonella Performance Standards - Basic Requirements			58. Specified Risk Materials (SRM)	X
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

Date: 08/29/2012 Est #: 2065 [S/P] (Argentina)

52/51 Cattle in one of the holding pens did not have access to water. This was corrected immediately. [9 CFR §313.2(e)]

58/51 Leakage of brain tissues (SRM) from the knocking hole of skinned head resulting in carcass head contamination with SRM. [9 CFR §310.22]

61. NAME OF AUDITOR

for Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

for Farooq Ahmad 8/29/12

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION FCO. Rioplatense S.A.I.C.I.F. General Pacheco Buenos Aires	2. AUDIT DATE 8/31/2012	3. ESTABLISHMENT NO. 1920	4. NAME OF COUNTRY Argentina
5. NAME OF AUDITOR(S) Farooq Ahmad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP)	Audit Results	Part D - Continued Economic Sampling	Audit Results
Basic Requirements			
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Specified Risk Materials(SRM)	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 08/31/2012 Est #: 1920 [S/P] (Argentina)

58/51 Leakage of brain tissues (SRM) from the knocking hole of skinned head resulting in carcass head contamination with SRM. [9 CFR §310.22]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

Farooq Ahmad 8/31/12

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Mirab S.A. Pilar, Buenos Aires	2. AUDIT DATE 9/3/2012	3. ESTABLISHMENT NO. 1067	4. NAME OF COUNTRY Argentina
5. NAME OF AUDITOR(S) Farooq Ahmad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Date: 09/03/2012 Est #: 1067 [P] (Argentina)

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

61. NAME OF AUDITOR

for
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

Ota Khan 9/3/12

APPENDIX B: Foreign Country Response to Draft Final Audit Report (when available)